Incidence and predictors of re-intervention after Novasure endometrial ablation: a validation study in patients with abnormal uterine bleeding with data extraction from the Electronic Health Record and a Clinical Data Collector.

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Data extraction with CDC to study the effectiveness of Novasure endometrial ablation is reliable compared to manual EHR data extraction

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20077

Bron
NTR

Verkorte titel
SEED

Aandoening

Abnormal Uterine Bleeding

Ondersteuning

Primaire sponsor: Máxima MC
Overige ondersteuning: Máxima MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Surgical re-intervention in Máxima MC in women with abnormal uterine bleeding who underwent Novasure treatment in 2018

Toelichting onderzoek

Achtergrond van het onderzoek

Endometrial ablation using Novasure is a treatment in which the endometrium is removed in women with abnormal uterine bleeding. Unfortunately, in 10-20% of women, surgical re-intervention in the form of another ablation or even a hysterectomy is required because initial treatment has failed. For this reason, it is important to identify prognostic risk factors which are associated with treatment failure, and to continuously and conveniently evaluate clinical data in order to improve the effectiveness of Novasure endometrial ablation.

The current standard for real-world data extraction from the Electronic Health Record (EHR) is manual search and review of free text in EHR. This is an inefficient, time-consuming and laborious process, which is difficult to monitor and reproduce and, moreover, it contravenes the General Data Protection Regulation (GDPR). Clinical Data Collector (CDC) is a text mining software tool to collect structured and unstructured data from the EHR in a pseudonymised way through a search query. The search can be saved and reused, which increases verifiability. Data extraction with CDC has the additional advantage that only data that is relevant for the search query (minimizing data extraction) is automatically requested and pseudonymised (i.e. GDPR security). With the use of CDC, the efficiency of data extraction can be greatly improved. However, the validity of the extracted data depends on the quality of the CDC search. This search must take into account the different ways of registering in EHR by care professionals. Preparing a good search query in CDC can therefore be a challenge and must be critically evaluated.

In this study, we want to evaluate whether EHR data extraction with CDC to study the effectiveness of Novasure endometrial ablation is reliable compared to manual EHR data extraction.

Doel van het onderzoek

Data extraction with CDC to study the effectiveness of Novasure endometrial ablation is reliable compared to manual EHR data extraction

Onderzoeksopzet

Primary outcome:
- Surgical reintervention measured during a follow-up of 2 years after Novasure endometrial ablation as recorded in the EHR by the healthcare professional.

Secondary outcomes as recorded in the EHR by the healthcare professional:
- Patient characteristics measured at the time of Novasure endometrial ablation. If not possible/available: measurement at a time point as close as possible to the intervention
- Time between Novasure endometrial ablation and re-intervention
- Pre-existent Tubal ligation (i.e. any time point before Novasure endometrial ablation)
- Pre-existent dysmenorrhea (i.e. any time point before Novasure endometrial ablation)
- Uterine position, preferably the last measurement before Novasure endometrial ablation
- Time and power ablation at the time of Novasure endometrial ablation
- Analgesia (sedation, treatment room, Operating Room) at the time of Novasure endometrial ablation

Onderzoeksproduct en/of interventie

Novasure endometrial ablation

Contactpersonen

Publiek

Máxima Medisch Centrum
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040-8887811

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Woman who suffer from abnormal uterine bleeding and who previously underwent Novasure treatment in 2018 in Máxima MC

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Previous surgical intervention for heavy menstrual bleeding

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	19-01-2021
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9268
Ander register	Commissie Lokale Uitvoerbaarheid Máxima Medical Center : L20.188

Resultaten